REMARKS

Claims 1 and 5 are amended. Claims 1-8 are pending and examined.

Support for Amendments

A sequence listing in computer readable format is submitted with this paper. Applicants respectfully request entry of the sequence listing. Support for the sequence listing can be found in original paragraphs [0013] and [0247].

Paragraphs [0013] and [0247] are amended to insert SEQ ID numbers according to USPTO practice. Paragraphs [0017], [0045], and [0073] are amended to correct a typographical error in the drawing for (-)-FTC (Emtriva). The structure of Emtriva is known and reported in the chemical literature, as described in paragraph [0017]. In addition, the chemical name is given at page 4, lines 15-16. The instant drawings are amended to agree with the chemical literature and the given chemical name. In addition, a grammatical correction ("shows") is inserted in paragraph [0017].

Claim 1 is amended to insert the full names for β-L-FTC and L-FMAU as suggested by the Examiner. Support can be found at page 4, line 15, and at page 5, lines 9-10.

Claim 5 is amended to capitalize the terms SuperFeron and HuFeron to be consistent with USPTO policy on trademarks as suggested by the Examiner.

No new matter is added.

Sequence Listing

The foregoing amendments are made to insert the required SEQ ID NO identifiers associated with each listed sequence.

Claim Objection

Claim 5 is objected to for the use of SuperFeron and HuFeron. In response, the terms have been capitalized to be consistent with the other terms in the claim. Applicants respectfully request withdrawal of the objection.

Rejections Under 35 U.S.C. § 112, 2nd paragraph

Claims 1-8 are rejected as being indefinite due to the terms β-L-FTC and L-FMAU. Applicants respectfully traverse on the basis that the terms are clearly defined in the specification. However, in order to advance prosecution, Applicants amend the claims to recite the full names for the abbreviations in claim 1, as suggested by the Examiner. Applicants respectfully request withdrawal of the rejection.

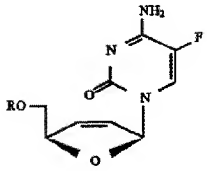
Rejections Under 35 U.S.C. § 102(b)

Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Schinazi et al (U.S. Patent 5,703,058). The Office Action states that Schinazi teaches 1) FTC for HBV at column 2, lines 40-41; 2) alpha interferon for HBV at column 2, lines 46-55; 3) and L-FMAU with the (-) enantiomer of FTC for HBV at column 6, lines 21-27.

Applicants respectfully traverse on the basis that Schinazi does not disclose a method for the treatment or prophylaxis of a human infected with hepatitis B virus comprising administering in combination or alternation an effective amount of 1) ß-L-FTC; 2) L-FMAU; and 3) interferon, or their pharmaceutically acceptable salts or prodrugs, independently optionally in pharmaceutically acceptable carriers. Specifically, in the passages cited by the

Office Action, Schinazi does not disclose the combination or alternation of the three components with each other. In fact, Schinazi discloses in claim 1 :

1. A composition comprising an effective HIV or HBV treatment amount of a compound of the formula:



wherein R is hydrogen, monophosphate, diphosphate, or triphosphate; in combination or alternation with a second compound selected from the group consisting of 2-hydroxymethyl-5-(5-fluorocytosin-1-yl)-1,3-oxathiolane, 2-hydroxymethyl-5-(cytosin-1-yl)-1,3-oxathiolane; 9-[4-(hydroxymethyl)-2-cyclopenten-1-yl]-guanine (carbovir), 9-[(2-hydroxyethoxy)methyl]guanine (acyclovir) interferon, 3'-deoxy-3'-azidothymidine (AZT), 2',3'-dideoxyinosine (DDI), 2',3'-dideoxycytidine (DDC), (−)-2'-fluoro-5-methyl-β-L-ARAuridine (L-(−)-FMAU) and 2',3'-didehydro-2',3'-dideoxythymidine (D4T).

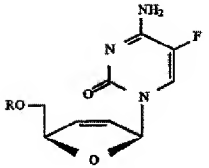
In other words, Schinazi discloses in claim 1 that each component individually can be combined or alternated as a second component with a first component of the formula disclosed at column 21, lines 1-11. In claim 1, Schinazi does not disclose the combination or alternation of the components with each other. The combination or alternation of the components with each other has been supplied by the Examiner in view of the present specification. Therefore, Schinazi does not anticipate claim 1. Applicants respectfully request withdrawal of the rejection.

Rejections Under 35 U.S.C. § 103(a)

Claims 1-8 are rejected under 35 U.S.C. § 103(a) as being anticipated by Schinazi et al (U.S. Patent 5,703,058) and Thyagarajan (U.S. Patent 6,589,570).

Applicants respectfully traverse on the basis that Schinazi does not teach a method for the treatment or prophylaxis of a human infected with hepatitis B virus comprising administering in combination or alternation an effective amount of 1) ß-L-FTC; 2) L-FMAU; and 3) interferon, or their pharmaceutically acceptable salts or prodrugs, independently optionally in pharmaceutically acceptable carriers. Specifically, in the passages cited by the Office Action, Schinazi does not teach the combination or alternation of all three components with each other. In fact, Schinazi teaches in claim 1 :

> **1. A composition comprising an effective HIV or HBV treatment amount of a compound of the formula:**



wherein R is hydrogen, monophosphate, diphosphate, or triphosphate; in combination or alternation with a second compound selected from the group consisting of 2-hydroxymethyl-5-(5-fluorocytosin-1-yl)-1,3-oxathiolane, 2-hydroxymethyl-5-(cytosin-1-yl)-1,3-oxathiolane; 9-[4-(hydroxymethyl)-2-cyclopenten-1-yl]-guanine (carbovir), 9-[(2-hydroxyethoxy)methyl]guanine (acyclovir) interferon, 3'-deoxy-3'-azidothymidine (AZT), 2',3'-dideoxyinosine (DDI), 2',3'-dideoxycytidine (DDC), (−)-2'-fluoro-5-methyl-β-L-ARAuridine (L-(−)-FMAU) and 2',3'-didehydro-2',3'-dideoxythymidine (D4T).

In other words, Schinazi teaches in claim 1 that each component individually can be combined or alternated as a second component with a first component of the formula taught at column 21, lines 1-11. In claim 1, Schinazi does not teach the combination or alternation of all the components with each other. The combination or alternation of the components with each other has been supplied by the Examiner in view of the present specification. This is impermissible hindsight reconstruction. Therefore, Schinazi does not render the instant claims obvious.

Thyagarajan as cited by the Office Action fails to cure the deficiency of Schinazi. The Office Action relies on Thyagarajan for a teaching that alpha, beta and gamma interferon are "agents that have been studied and are successful in the treatment of HBV infection" (Office Action, page 6, lines 10-11). However, the Office Action appears to mischaracterize the Thyagarajan reference in suggesting that it teaches that interferons "are successful in the

treatment of HBV infection" as stated in the Office Action. In fact, Thyagarajan teaches away from the use of interferons. Table 1 is actually entitled "Agents that have been studied in the treatment of HBV infection" (see Thyagarajan, col. 2, lines 23-25). There is no mention in the table of successful treatment. On the contrary, Thyagarajan teaches that most of the entries in the table are "far from successful" (Thyagarajan, col. 2, lines 41-42). Furthermore, Thyagarajan actually characterizes the interferons as having "limited success rate, prohibitive cost, profound side effects" and also as being non-accessible (see Thyagarajan, col. 2, lines 42-44). Thyagarajan concludes that it is necessary to search for newer agents for treatment of HBV infection. When taken as a whole, the Thyagaran reference relied upon by the Office Action teaches away from the use of interferons.

In summary, i) Schinazi fails to teach the combination or alternation of the required components with each other, ii) Thyagarajan teaches away from the use of interferons, and iii) the Office Action relies on improper hindsight reconstruction. Therefore, Applicants respectfully request withdrawal of the rejection.

CONCLUSION

Based on the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims and allowance of this application.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **50-3732**, Order No. 04674.105074 (TRI 1016).

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to

grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **50-3732**, Order No. 04674.105074 (TRI 1016).

Respectfully submitted,
King & Spalding, LLP

Dated: April 17, 2007 By: 

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